UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOANNE NORIEGA, on behalf of herself, all others similarly situated, *Plaintiff*, v. ABBOTT LABORATORIES, *Defendant*.	Case No. 1:23-cv-04014-PAE

ABBOTT LABORATORIES' REPLY
IN SUPPORT OF MOTION TO DISMISS

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INTRODUCTION

Nothing in Plaintiff Joanne Noriega's Opposition can overcome the fundamental problem with her theory of liability: While her claims are premised on the notion that Abbott is "[w]ithout ***any*** scientific support" (Compl., ECF No. 1 ¶ 5) that PediaSure® helps kids grow in height, her own Complaint references precisely the support she says does not exist.

The Opposition concedes that, to plead an actionable violation of General Business Law ("GBL") §§ 349 and 350, the challenged statement must be likely to mislead a reasonable consumer acting reasonably under the circumstances. Yet the Opposition confirms that the Complaint does not state a claim under that standard. This is because the Opposition outright acknowledges that Noriega has based her claims on the theory that no clinical proof exists for the statement that PediaSure® is "Clinically Proven to Help Kids Grow" even though the Complaint references several published clinical studies that expressly find PediaSure® leads to height gains.

The Opposition's answer to this is to attempt to nitpick the supporting studies' methodologies. But such criticisms do not mean the label statement that the studies support is materially misleading; Noriega cites no case holding otherwise. And Noriega's nitpicks are meritless. Her chief criticism is that the supporting studies involved—in Noriega's words—children in the so-called "Third World" rather than the "kinds of kids" in New York. Pl.'s Mem. of Law in Opp'n ("Opp'n") at 15. But that is a distinction without a difference; Noriega nowhere explains why the nutritional needs of any given child hinges on his or her country of origin. In any case, that distinction is fully accounted for by clarifying language on the front of every PediaSure® bottle stating that the "helps kids grow" claim was "[s]tudied in children at risk for malnutrition." *See* Abbott's Mem. in Supp. Of Mot. to Dismiss, ECF No. 18 ("Mot.") at 11 & ECF No. 19-1. Under well-worn New York law, this clarifying statement alone dooms Noriega's

theory that the challenged statement is materially misleading. The Complaint should be dismissed.

ARGUMENT

A. Noriega's Opposition cannot overcome the clinical studies referenced in the Complaint, which render her claims implausible as a matter of law.

Noriega's Opposition doubles down on the Complaint's conclusory theory that Abbott is "[w]ithout any scientific support" for the proposition that PediaSure® helps kids grow. Compl. ¶ 5. Noriega argues, for instance, that "the simple fact is that proof of Defendant's Clinically Proven Claim **does not exist**." Opp'n at 15 (emphasis in original).

But her own pleading "itself in effect concedes that substantiation does exist." *See Greifenstein v. Estee Lauder Corp., Inc.*, 2013 WL 3874073, at *4 (N.D. Ill. July 26, 2013). For example, the Complaint references one study that found that "***[h]eight-for-age percentiles*** increased steadily over time and became significantly higher than baseline from week 24 onwards" after children began consuming PediaSure®. Huynh, *et al.*, *Longitudinal growth and health outcomes in nutritionally at-risk children who received long-term nutritional intervention*, J. of the British Dietetic Ass'n, at 623 (2015) (emphasis added). Another example found "significantly greater increases" in, among other measures, "***height***" and "***height-for-age***" percentiles in the study group taking PediaSure® than in the control group. Alarcon, *et al.*, *Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters*, Clinical Pediatrics, at 209, 211, 213-214, 216 (April 2003) (emphasis added); *see also* Fisberg, *et al.*, *Effect of Oral Nutritional Supplementation with or without Symbiotics on Sickness and Catch-up Growth in Preschool Children*, Int'l Pediatrics, at 219 (2002) (finding increases in "height," among other measures, "as measured by increasing percentiles over time"); Mot. at 6.

Faced with the clinical proof she says does not exist, Noriega tries to gin up a factual dispute in several ways, none of which is availing. ***First***, Noriega misstates the law. Noriega

posits that "it is well settled, that factual disputes over whether the scientific literature supports the truth or falsity of a product's claims cannot be properly resolved on a motion to dismiss." Opp'n at 16. But the law is clear that "where a plaintiff has chosen to use scientific studies in an effort to raise plausible inferences that marketing is deceptive, and the studies cited do not support her claims, the plaintiff has not plausibly pleaded her claims." *Bermudez v. Colgate-Palmolive Co.*, --- F. Supp. 3d ---, 2023 WL 2751044, at *8 (S.D.N.Y. Mar. 31, 2023) (quotations omitted); *Housey v. Proctor & Gamble Co.*, 2022 WL 874731, at *6 (S.D.N.Y. Mar. 24, 2022), *aff'd*, 2022 WL 17844403 (2d Cir. Dec. 22, 2022); Mot. at 6-7 (collecting cases). In other words, where studies relied upon in a complaint contradict a plaintiff's allegations, the studies themselves control—*not* plaintiff's characterization of them. *See Housey*, 2022 WL 874731, at *6.

Noriega tries to resist the force of the numerous cases cited in Abbott's opening brief that support this point by arguing that they "involved claims that were not scientifically supported by the Plaintiff in those cases"—*i.e.*, cases where plaintiffs cited competing scientific studies that they contended affirmatively showed the defendants' claims were materially misleading. Opp'n at 17. But the case for dismissal here is even stronger. Noriega has not brought to the table scientific proof of her own ***disproving*** the challenged statement—which the plaintiffs in dismissed cases like *Bermudez* at least tried to do—but instead merely criticizes and mischaracterizes Abbott's studies.

Noriega's cited cases only underscore why dismissal is appropriate. For example, Noriega relies on *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131 (E.D.N.Y. 2015). *See* Opp'n at 16. But the court there granted dismissal of GBL claims after analyzing the plaintiffs' cited studies and concluding that they failed to "raise plausible inferences that [the defendant's] claimed health benefits [were] simply not true." *Id.* at 141. This was true even though "plaintiffs point[ed] to scientific studies that they allege actually disprove[d] [the] product's claims." *Id.* at 138 (noting

the "stark disconnect between the scientific studies" and the plaintiffs' claims and finding it "fatal to plaintiffs' complaint"). As another example, Noriega relies on *Sitt v. Nature's Bounty, Inc.*, 2015 WL 5372794 (E.D.N.Y. Sept. 26, 2016). *See* Opp'n at 16. But that case provides an illustrative contrast to this case. There, the complaint did not incorporate by reference studies that supported the defendant's labeling claim. *Id.* at *10. Instead, the complaint relied on outside studies that affirmatively supported the plaintiff's position that the labeling claim was false. *Id.* Noriega has taken a materially different tack here, choosing instead to cite in her own Complaint the very studies providing the clinical proof she claims does not exist, thereby putting those supportive studies in play on a motion to dismiss.

Second, Noriega misstates the findings of the studies that provide the clinical proof that is supposedly missing, including the following:

- ***Alarcon, et al.* (2003):** Noriega argues that this study "was not able to empirically demonstrate any increase in height due to consumption of" PediaSure®. Opp'n at 10. That contradicts the study itself, which expressly found "significantly greater increases" in height and height-for-age percentiles in the study group taking PediaSure® than in the control group. Noriega also tries to make hay out of the study's statement that "the mechanisms underlying catch-up growth are not clearly understood." Opp'n at 10. But the state of understanding of the "mechanisms" of one particular type of growth does not change that this study found clinical proof of the very height gains Noriega posits are unsupported by clinical proof.

- ***Fisberg, et al.* (2002):** Noriega misstates the findings of this study too, stating that it "did not study PediaSure's ability to help kids grow taller" and that "no conclusion could be made on the ability of PediaSure alone to help children grow taller." *Id*. at 10. Not so. The study itself explicitly found height gains in both the study group of children given PediaSure® with synbiotics and the study group given PediaSure® without synbiotics—including increases compared to other children their age (*i.e.*, "increasing percentiles over time").

- ***Huynh, et al.* (2015):** Noriega does not dispute this study expressly found height gains but instead argues that the study lacked a control group. Opp'n at 9. This, however, ignores the authors' own explanation that even so "the probability that the [PediaSure®] resulted in the health benefits observed in the present study is high."

Noriega also argues that the supporting studies referenced in the Complaint involved different formulations of PediaSure®. Opp'n at 11-12. But none of the facts on which Noriega relies for this newfound argument are in the Complaint. Nor does Noriega explain in her Opposition—much less in the Complaint—how any variations in formulation would make any material difference, much less nullify every one of the supporting studies. This is yet another trumped-up nitpick that, for the reasons explained below, is not enough to withstand dismissal.

Third, Noriega misstates the findings of the two 2018 Ghosh articles and the 2021 Khanna article, repeatedly arguing that they affirmatively found that PediaSure® does not increase height. *E.g.*, Opp'n at 9 (Ghosh studies "concluded that there was no evidence that PediaSure helped to increase height"); *id.* at 16 (studies "clearly conclude that consuming PediaSure, even by children at risk for malnutrition, does not help them grow taller").

Not so. None of these three studies finds that PediaSure® does ***not*** help kids grow in height. To the contrary, these studies show height gains. Ghosh's follow-up study states that children "who self-supplemented [with PediaSure®] from Day 90 to Day 210 had a greater increase in weight change, and, [albeit] to a lesser extent, ***height gain***." Ex. 6 at 2628–29 (emphasis added). And Khanna's 2021 study found "a trend toward greater ***height gain*** compared to [the control group]." Ex. 7. at 1 (emphasis added).[1] Thus, far from Noriega's self-serving mischaracterization that the Ghosh and Khanna studies affirmatively found that PediaSure® does not increase height, those studies actually saw height gains albeit not statistically significant ones.

[1] Noriega also relies on the Lampl article—which she calls a "study"—criticizing the benefits of oral nutrition supplements like PediaSure®. Opp'n at 10–11 & n.13. But this was not a clinical study; it did not, for example, test PediaSure's effect on children's height. *See* Lampl, *Promoting Healthy Growth or Feeding Obesity? The Need for Evidence-Based Oversight of Infant Nutritional Supplement Claims*, Healthcare (Basel), 2016 Nov 12;4(4):84. All this paper does is offer methodological criticisms of others' clinical work that, like Noriega's own criticisms, cannot salvage Noriega's claims for the reasons set out below. *See infra* § B.

That the Ghosh and Khanna studies did not find statistically significant height gains is the result of their design and limitations, primarily their relatively short duration. The studies themselves make this clear. For example, the first Ghosh article explains that "a longer treatment period may be necessary for significant improvement in height." Brancato Decl., Ex. 5 at 2198. Ghosh's follow-up study likewise refers to the short initial study period and the fact that participants' consumption of PediaSure® was inconsistent during the follow-up period. Brancato Decl., Ex. 6 at 2628–29. The 2021 Khanna study also notes its relatively short duration and its implications, explaining that "[p]revious studies have shown that height improvement was only observed with intervention of longer duration (>6 months)." Brancato Decl., Ex. 7. at 10.

These three studies are therefore fully consistent with Abbott's "help kids grow" statement, which does not claim that PediaSure® helps kids grow within any particular timeframe—be it one day or one week or one year. Nor, contrary to Noriega's suggestion otherwise, are these three studies inconsistent with the Alarcon, Fisberg, and Huynh studies. As the first Ghosh article puts it, the 2015 Huynh study "showed a significant improvement in height from baseline" at week 24 onwards, which simply means that "a longer treatment period may be necessary for a significant improvement in height." Brancato Decl., Ex. 5 at 2198. That is exactly Abbott's point.

Finally, Noriega misstates the challenged statement itself. Like the Complaint, the Opposition presumes that the statement guarantees that PediaSure® is some elixir that always makes every kid taller. *E.g.*, Opp'n at 4 (criticizing Abbott for recording revenue from PediaSure® sales even though PediaSure® "is not a cure for shortness"); *id.* at 12 (alleging that Plaintiff's grandson "was still short for his age" despite consuming PediaSure®). It is against this imagined guarantee of height gains that Noriega then measures the clinical studies' findings. *See*, *e.g.*, *id*.

at 16–18. But the actual statement at issue is that PediaSure® is "Clinically Proven to ***Help*** Kids Grow." For that statement, Noriega cannot plausibly claim that clinical proof does not exist.[2]

B. Noriega's misplaced distinction between "average American children" and children in the so-called "Third World" cannot salvage her claims.

In light of the clinical proof that PediaSure® helps kids grow in height, Noriega spends much of her Opposition seeking to undermine the supporting studies' methodologies. Opp'n at 1–2, 9–12, 15–16, 18–23. But attacking the methodologies of studies supporting a claim of clinical support is not enough to plausibly state a claim for false advertising. *Greifenstein v. Estée Lauder Corp., Inc.*, 2013 WL 3874073, at *4 (N.D. Ill. July 26, 2013) (dismissing false advertising claim where complaint itself established that there was clinical proof for a "clinically proven" claim despites plaintiff's "quarrel[s]" with the study's methodology); *In re Riddell Concussion Reduction Litig.*, 121 F. Supp. 3d 402, 416 (D.N.J. 2015) ("[A]s this Court and others have recognized, identifying flaws in a scientific study does not necessarily make marketing statements based on such a study false or misleading."). Otherwise, plaintiffs could always survive a motion to dismiss in lawsuits challenging an advertising claim indicating clinical support, because any clinical study can be criticized in some way. Critically, Noriega's Opposition does not cite a single case rebutting the legal principle that challenges to the methodology used in studies supporting an advertising claim are insufficient to defeat a motion to dismiss in circumstances like these. *Compare* Mot. at 10-11, *with* Opp'n at 15-18.

Nor does the particular methodological attack on which Noriega focuses her Opposition—

[2] Noriega's Opposition also twice misquotes the claim at issue as "clinically proven to help kids grow ***and gain***," including on the first page. *See* Opp'n at 1, 15 (emphasis added). As the Complaint makes clear, the claim at issue is "Clinically Proven to Help Kids Grow." *E.g.*, Compl. ¶¶ 5, 26, 34 (image of PediaSure® label), *id*. ¶¶ 44, 54 (defining class as New York purchasers who bought PediaSure® products labeled "Clinically Proven to help kids grow").

that the supporting studies were not conducted in the United States—pass muster.[3] In Noriega's telling, the claim is misleading because "all of the clinical studies of PediaSure focus on children in countries with high levels of under- or malnourished children." Opp'n at 1, 9.

This is a distinction without a difference. Noriega fails to explain how a particular child's nutritional needs would differ by his or her country of origin. Indeed, despite relying on a distinction between "First" and "Third World" countries, Noriega does not so much as explain which countries qualify as which. *See* Opp'n at 1, 3, 9, 15. Nor does she define which kids qualify as what the Opposition refers to as "average American children" or the "kinds of kids" in New York and which do not. *Id.* at 9, 15. Further, that the incidence of under-nourishment and stunting is higher in other countries does not mean it is non-existent in the United States. The Opposition itself concedes that under-nourishment remains a real and serious threat to some children in the United States, stating that 3% of children in the United States suffer from moderate to severe stunting. *Id*. at 4. That means, per Noriega, millions of American children suffer from stunting.

Regardless, the challenged statement itself includes a disclosure that accounts for Noriega's methodological criticism by explaining that this proposition has been "studied in children at risk of malnutrition." *See* Brancato Decl., Ex. 1; Compl. ¶¶ 27-28; Mot. at 12. This disclosure is referred to ***in the middle of the claim itself***, via a superscript notation directing potential purchasers to the clarifying language:

[3] Noriega's Opposition also criticizes the studies that provide clinical support for the "helps kids grow" statement as supported by Abbott. *E.g.*, Opp'n at 11 (referring to the studies' "inherent confirmation bias as Abbott funded, with Abbott employees as lead researchers"). Noriega's position seems to be that Abbott must have clinical proof—but that Abbott can have no role in arranging clinical studies that may (or may not) provide that proof. Also, Noriega's position seems to be that the studies that constitute the clinical proof that PediaSure® helps kids grow in height are tainted by Abbott's support—but the 2018 Ghosh and 2021 Khanna studies are not. None of this makes sense as companies regularly sponsor and/or participate in clinical studies of their products. Even if it did, it would not be enough to forestall dismissal, as the fact that Abbott sponsored the studies simply does not mean they are not clinical proof.

Id. This notation and corresponding statement dispel any confusion a reasonable consumer might have about in what population PediaSure® has been clinically proven to help kids grow.

Where the label dispels any possible confusion via a clarification like that here, New York courts commonly dismiss GBL claims. *E.g.*, *Melendez v. ONE Brands, LLC*, 2020 WL 1283793, at *7 (E.D.N.Y. Mar. 16, 2020); *Richardson v. Edgewell Pers. Care, LLC*, --- F. Supp. 3d ---, 2023 WL 1109646, at *4 (S.D.N.Y. Jan. 30, 2023); *Turk v. Rubbermaid Inc.*, 2022 WL 836894, at *8 (S.D.N.Y. Mar. 21, 2022); Mot. at 12–13. As one of the cases Noriega relies on explains, "[i]n determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial[,]" and "the presence of a disclaimer or similar clarifying language may defeat a claim of deception." *Fink v. Time Warner Cable*, 714 F.3d 739, 741–42 & n.2 (2d Cir. 2013).

In arguing for a different result, Noriega relies heavily on *Mantikas v. Kellogg Co.*, 910 F.3d 633 (2d Cir. 2018). *See* Opp'n at 18–20. But dismissal here would be fully in line with *Mantikas*. *Richardson*, for instance, relied on *Mantikas* in explaining why the label challenged in that case (which featured an asterisk leading to clarifying language) was not deceptive, explaining that *Mantikas* reinforced the principle that courts should "consider the challenged [label] as a whole, including disclaimers and qualifying language." *See* 2023 WL 1109646, at *5. Indeed,

"[s]ince *Mantikas*, courts in this Circuit have reasoned that [i]f a plaintiff alleges that an element of a product's label is misleading, but another portion of the label would dispel the confusion, the Court should inquire as to whether the allegedly misleading element is instead merely ambiguous," in which case "the clarification can defeat the claim." *Bynum v. Fam. Dollar Stores, Inc.*, 592 F. Supp. 3d 304, 310–11 (S.D.N.Y. 2022). Here, no reasonable consumer interested in the "clinically proven" claim would ignore the superscript notation in the claim itself. *E.g.*, *Warren v. Whole Foods Mkt. Grp., Inc.*, 574 F. Supp. 3d 102, 115 (E.D.N.Y. 2021); *Piescik v. CVS Pharmacy, Inc.*, 576 F. Supp. 3d 1125, 1134–35 (S.D. Fla. 2021).

This is particularly true where, as here, the notation and corresponding clarifying statement are on the same side of the label; in this case, the front. This distinguishes the present case from those cited by Noriega, where the clarifying language appeared on the rear of the package or on entirely different pages or forms. *See, e.g.*, *Mantikas*, 910 F.3d at 637 (language on side of box); *Fishon v. Peloton Interactive, Inc.*, 2020 WL 6564755, at *4 (S.D.N.Y Nov. 9, 2020) (separate terms of service); *Rivera v. Navient Sols., LLC*, 2020 WL 4895698, at *9 (S.D.N.Y. Aug. 19, 2020) ("fine print" on second page of bill); *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 479-80 (S.D.N.Y. 2014) (back of label). In fact, one case cited by Noriega—*Stoltz v. Fage Dairy Processing Indus.*, 2015 WL 5579872 (E.D.N.Y. Sept. 22, 2015)—relied on the ***lack*** of any asterisk-like notation when denying dismissal, finding that there were no "obvious signals" linking the phrase "Total 0%" with the explanatory language "nonfat" such that reasonable consumers need not "infer the connection" between the two. *Id.* at *15. Here, the link is clear; no reasonable consumer could miss it. This is yet another reason Noriega's methodological nitpicking fails.

CONCLUSION

The Court should dismiss Noriega's Complaint.

Dated: September 25, 2023

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 25th day of September 2023, a true and correct copy of the foregoing document and attachments were served upon all counsel of record.

/s/ Michael A. Glick
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